



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,116	12/22/2003	Robert W. Olsen	P-11209.07	8483
27581	7590	06/08/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER

3761

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/743,116	Applicant(s) OLSEN ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-33, 35, 41 and 42 is/are rejected.
- 7) ☒ Claim(s) 25, 34, 36-40, 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) <u>5/9/05</u>
Paper No(s)/Mail Date <u>3/12/04; 2/14/05; 2/28/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 6 and 26 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 depends from claim 4, and comprises the same limitations of claim 4, thereby failing to further limit the structure of the device claimed in claim 4. The text of claim 26 is identical to that of claim 24, failing to further limit the prior claim 24.

Drawings

2. The drawings are objected to because the lines are unclear and several reference numbers are illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 7, 18-23, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,730,267 to Stringer et al in view of US 6,495,366 to Briggs.

In the specification and figures, Stringer discloses the apparatus and method as claimed by applicant. With particular regard to claims 1 and 21, Stringer discloses a blood handling system 30 as a component of an extracorporeal blood circuit 10 (see column 4, lines 32-37). The blood handling system comprises an air removal device with a housing 40 that defines a chamber or gas collection plenum 50 with a gas removal port 46 connected to the plenum (see, generally, column 5, FIG 3). The port comprises an air sensor 37 and a valve 36. The gas removal port is connected to suction line 35 that is connected to a vacuum source 34 (see FIG 1). The valve and the sensor are coupled to controller 33 so that the controller can automatically operate the

valve in response based on feedback from sensor 37 that opens and closes valve 36 (see column 7, lines 15-28, column 5, lines 3-15).

With regard to applicant's "means responsive to" and "means for" limitations, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification appears to define the means for conducting the claimed operations as a controller 400. Since Stringer discloses a controller 33 that is capable of performing the claimed operations, the Stringer disclosure meets these limitations of the claims.

Stringer fails to disclose that the controller circuitry has a self-test and standby mode. However, Briggs discloses an extracorporeal blood circuit with a processor that controls blood flow with a self-test, standby, and automatic mode in order to ensure that the device is functioning properly before obtaining patient blood (see column 11, generally). In particular, Briggs discloses that the processor 100 may execute a self-test upon powering up and programming by the operator (see column 11, lines 18-25) that

tests operating conditions of the circuit. After the tests are completed, the processor enters a standby mode before priming in which a “ready to prime” message is displayed, indicating that the system is in standby, waiting for operator input. Finally, the processor may operate in an automatic mode that controls the circuit.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a self-test mode and a standby mode as disclosed by Briggs to the automatic mode of the controller and air removal system disclosed by Stringer in order to ensure that the extracorporeal circuit is in operational condition before removing blood from the patient, as taught by Briggs.

With regard to claims 2, 3, 22, 23, Stringer discloses that the system comprises electrical lines and a back-up battery in base 220, indicating that the device comprises a power supply that is powered by electrical lines or the backup battery. Stringer further discloses that the display includes an indicator of battery status as determined by controller 33, which may comprise an alert if the backup battery is failing (see column 10, lines 28-55).

With regard to claims 7, 18, 20, 27, 28, 30 the controller comprises a display 225 that serves as a display of system function and status and may comprise a graphic display (comprising a lighted visual alerting means) that displays help (or error) messages (see column 10, lines 28-43, column 11, lines 1-10).

With regard to claims 19 and 29, Briggs specifically discloses that the controller comprises an audible alarm upon detection of an error signal (see column 8, lines 60-65).

5. Claims 8-9, 11-17, 31-33, 35, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,730,267 to Stringer et al in view of US 6,495,366 to Briggs, further in view of US 6,337,049 to Tamari.

In the specification and figures, Stringer and Briggs disclose the device substantially as claimed by applicant (see rejection above) with the exception of a fluid-in-line sensor. With particular regard to claim 9, Tamari discloses a venous reservoir 1819 with outer walls 18, 19 that enclose a chamber 2. The reservoir comprises a purge port or outlet tube 4 connected to the chamber 2 with a sensor or detector 10 and monitor/controller 10 that alerts the user to the presence of air entering the tube (see column 10, lines 5-35). The purge port may be connected to a suction source 1114 (see FIGS 1, 2, column 9, lines 20-23). The assembly further comprises valve or clamp (not shown) on the purge line that may be opened and closed in response to signals from monitor/controller 12 (see column 10, lines 25-27). The monitor/controller 12 may generate an alarm signal when air enters the outlet tube, alerting the user to the status of the device. Tamari discloses that sensor 10 is responsive to detect the presence of air as well as the presence of rising liquid (see column 10, lines 1-28). Since the detector and controller disclosed by Tamari is capable of functioning as claimed by applicant, it meets the limitations of the claim. It would have been obvious to one having ordinary skill in the art at the time of invention to incorporate the fluid-in-line sensor and control protocol disclosed by Tamari in the circuit and air purge device disclosed by Stringer and Briggs in order to prevent fluid from being expelled through the air purge port, as taught by Tamari.

With regard to applicant's "means for powering," "means for processing," and "means for inhibiting" limitations, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification appears to define the means for conducting the claimed operations as a controller 400 without any further structural limitations. Since Stringer, Briggs, and Tamari all disclose a controller that is capable of performing the claimed operations, the combined disclosures meet these limitations of the claims

With specific regard to claims 8, 11-16, 31-33, and 35, Tamari specifically discloses that the method includes the step of alerting the user or perfusionist under certain circumstances, such as the presence of air in the purge port. Such circumstances may be considered an "error state" as claimed by applicant and may control the suction valve based on information from controller 12 (see column 10, lines 20-25). Therefore, the Tamari disclosure meets the limitations of the claims.

With regard to claims 17 and 41-42, Tamari discloses that purge valve may comprise a solenoid actuated tubing clamp, meeting the limitations drawn to a pinch valve and the method of opening the pinch valve (see column 10, lines 25-28). The valve on the purge line that may be opened and closed in response to signals from monitor/controller 12 (see column 10, lines 25-27).

6. Claims 4-6, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,730,267 to Stringer et al in view of US 6,495,366 to Briggs, further in view of US 4,710,165 to McNeil et al.

In the specification and figures, Stringer and Briggs disclose the device substantially as claimed by applicant (see rejection above) with the exception of a manual, mechanical purge valve release. McNeil discloses a device that provides suction to a patient's body with a vacuum connected to a fluid chamber that comprises a valve to control the vacuum (see column 5, lines 23-45). McNeil further discloses that the valve may be manually activated in order to allow only air, and not liquid, to exit via the air suction port (see column 12, lines 41-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system disclosed by Stinger and Briggs with a manually activated purge valve as disclosed by McNeil in order to allow the operator to permit only air to escape from the air purge port.

With specific regard to claim 5, applicant claims a "means responsive to," which examiner is interpreting to be equivalent to the controller disclosed by Stringer and

Art Unit: 3761

Briggs. Since Stringer and Briggs disclose a controller that is capable of performing the claimed operations, the combined disclosures meet these limitations of the claims

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,730,267 to Stringer et al in view of US 6,495,366 to Briggs, in view of US 6,337,049 to Tamari, further in view of US 4,710,165 to McNeil et al.

In the specification and figures, Stringer, Briggs, and Tamari disclose the device substantially as claimed by applicant (see rejection above) with the exception of a manual, mechanical purge valve release. McNeil discloses a device that provides suction to a patient's body with a vacuum connected to a fluid chamber that comprises a valve to control the vacuum (see column 5, lines 23-45). McNeil further discloses that the valve may be manually activated in order to allow only air, and not liquid, to exit via the air suction port (see column 12, lines 41-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system disclosed by Stinger and Briggs with a manually activated purge valve as disclosed by McNeil in order to allow the operator to permit only air to escape from the air purge port.

Allowable Subject Matter

8. Claims 25, 34, 36-40, 43, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method claimed by applicant. In particular, the prior art fails to disclose or suggest the steps of providing the claimed device and controller wherein the controller performs the claimed self-test, monitoring, and movement procedures claimed by applicant, along with the other steps and limitations of the claims.

The best prior art of record, US 6,730,267 to Stringer and US 6,337,049 to Tamari, disclose the apparatus and a controller substantially as claimed by applicant, but fail to disclose or suggest the specific protocols carried out by the controller in the claimed method.

Conclusion

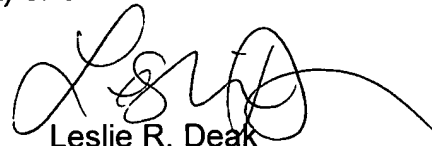
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,540,653 Schock et al
 - i. Bypass circuit with purge port
- b. US 5,823,986 Peterson
 - ii. Perfusion system with air purge and suction


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
26 May 2006



PATRICIA BIANCO
PRIMARY EXAMINER
5/30/06